



September 30, 2021

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Submitted electronically to:

[https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#blocktabs-uscdi\\_data\\_class\\_element\\_list-2](https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#blocktabs-uscdi_data_class_element_list-2)

**Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 3**

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability (USCDI) Version 3 and related data classes standards and elements. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

We appreciate this on-going collaborative process. HL7's feedback on the Draft USCDI v3 is detailed below. We offer overarching comments, recommendations to increase the value of USCDI with greater alignment to HL7 FHIR, and a table containing recommendations pertinent to each data class. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Decision Support, Clinical Quality Information, Orders and Observations and Patient Empowerment. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@HL7.org](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles Jaffe", with a stylized flourish at the end.

Charles Jaffe, MD, PhD  
Chief Executive Officer  
Health Level Seven International

A handwritten signature in black ink, appearing to read "Walter G. Suarez", with a stylized flourish at the end.

Walter G. Suarez, MD, MPH  
Board of Directors, Chair  
Health Level Seven International

## HL7 Overarching Responses to ONC's Draft USCDI v3

**Recommendation: Pilot Testing of USCDI Candidates** – HL7 recommends ONC support pilot testing of USCDI candidates for potential inclusion of certain specific Level 1 items in USCDI version 3, as most of these items represent discrete, granular data elements that are significant for direct clinical care, as well as research and clinical decision support and measurement.

It is vitally important to add the recommended new data elements to USCDI V3 so that they can be actively tested, with the intent to obtain input that will inform recommendations future USCDI editions.

**Recommendation: Seek Stakeholder and Industry Input on Evaluation Tools** – There are a variety of stakeholder perspectives on appropriate solutions to complex USCDI-related evaluation tooling issues such as those with structured assessment questionnaires, and other approaches to gathering necessary evaluation data. HL7 recommends ONC address these questions by seeking stakeholder input and conducting a forum to seek broad industry-wide solutions.

### Recommendations by Data Class

HL7's comments on ONC's Draft USCDI v3 by data class are in the chart below.

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
Encounter information	<a href="#">Encounter Diagnosis</a> <ul style="list-style-type: none"><li>• SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, March 2021 Release</li><li>• International Classification of Diseases ICD-10-CM 2021</li></ul> <a href="#">Encounter Disposition</a> <a href="#">Encounter Location</a>	Please clarify the relationship between Encounter.class in FHIR and the USCDI Encounter.type. As listed, Encounter type is ambiguous; especially since the USCDI Encounter type has no clear definition. <ul style="list-style-type: none"><li>• US Core includes Encounter.type which is basically an extensible list of encounter codes such that a clinical decision support artifact or quality measure could seek to retrieve any of a specific value set of encounters (i.e., Encounter.type).</li><li>• US Core also includes Encounter.class references “classes” of encounters (inpatient, ambulatory, virtual, emergency department, etc.) and this Encounter.class element has significant value for aggregate analysis</li></ul>

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<a href="#">Encounter Time</a> <a href="#">Encounter Type</a>	<p>to roll up all encounters of the same “class” for evaluation (including for use in clinical decision support artifacts or quality measures). Including “Encounter.class” also allows users of a set of CDS artifacts or quality measures to quickly search for only measures of one “class” without having to evaluate all encounter codes (Encounter.type) listed in the respective value set. This capability reduces the burden of CDS and eCQM / dQM implementers to identify the appropriate CDS artifacts or measures to address.</p> <p>HL7 strongly recommends that USCDI clearly define what is meant by Encounter.type and that USCDI include <u>both</u> Encounter.type <u>and</u> Encounter.class.</p>
	<p><b><u>Comment section:</u></b></p> <a href="#">Encounter Identifier</a> <a href="#">Encounter Participant</a> <a href="#">Encounter Participant Time Period</a> <a href="#">Encounter Status</a> <a href="#">Encounter Subject</a> <a href="#">Location Associated Time Period</a> <a href="#">Reason for the Encounter</a>	<p>Encounter participants can be useful and HL7 recommends adding this element to USCDIv3.</p>
Immunizations	<a href="#">Immunizations</a>	
	<p><b>Level 2</b></p> <a href="#">Immunization Code</a>	HL7 recommends adding Immunization Administered Date

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<p> <a href="#">Immunization Status</a>  <a href="#">Reason Immunization Not Performed</a>  <a href="#">Vaccination Administration Date</a>  <a href="#">Vaccination Event Record Type</a> </p> <p><b>Comment:</b></p> <p> <a href="#">Texas Disaster Consent</a>  <a href="#">Texas IIS Consent Date</a>  <a href="#">Texas Consent Status</a> </p>	<p>(which is a duplicate of Vaccine Administration Date), Immunization Code, Immunization Status, Reason Immunization Not Performed and Vaccination Event Record Type in version 3</p>
Laboratory	<p><a href="#">Tests</a></p> <ul style="list-style-type: none"> <li>Logical Observation Identifiers Names and Codes (LOINC®) version 2.70</li> </ul> <p><a href="#">Values/Results</a></p>	<p>HL7 recommends clarification that both performed date and reported date are needed.</p>
	<p> <a href="#">Laboratory Result Status</a>  <a href="#">Laboratory Result Value</a>  <a href="#">Laboratory Results: date and timestamps</a>  <a href="#">Laboratory Test Performed Date</a> </p>	

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<a href="#">Laboratory Test Panel Code</a>	
<b>Medication</b>	<a href="#">Medications</a>	
	<b>Level 2</b> <a href="#">Date Medication Administered</a> <a href="#">Date Medication Prescribed</a> <a href="#">Discharge Medications</a> <a href="#">Dosage</a> <a href="#">Medication Administered Code</a> <a href="#">Medication Administered Performer</a> <a href="#">Medication Administered Reason Reference</a> <a href="#">Medication Administration</a> <a href="#">Medication Administration Dose</a> <a href="#">Medication Administration Dose Units</a> <a href="#">Medication Prescribed Code</a> <a href="#">Medication Prescribed Dose</a> <a href="#">Medication Prescribed Dose Unites</a> <a href="#">Medication Prescribed</a>	HL7 recommends adding Date Medication Administered, Date Medication prescribed (must have code, dose and units), Discharge Medications, Dosage (must include units), Medication Administered Code, Medication Administered Performer; Medication Administered Reason reference, Medication Administration, Medication Administration Dose (how is this different from "dose"), Medication Dispensed; and Not given reason.

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<a href="#">Reason Reference</a> <a href="#">Medications Dispensed</a> <a href="#">Negation Rationale</a>	
	<b>Level 1</b> <a href="#">Medication Usage</a> <a href="#">Treatment Intent</a>  <b>Comment:</b> <a href="#">Medication Adherence Factor</a> <a href="#">Medication Experience</a>	
<b>Observations</b>	<a href="#">Observation Code</a> <a href="#">Observation Performer</a> <a href="#">Observation Subject</a> <a href="#">Observation Timing</a> <a href="#">Observation Value</a>	
	<b>Comment:</b> <a href="#">Apgar Score</a> <a href="#">Estimated Date of Delivery</a> <a href="#">Gestational Age</a> <a href="#">Gestational Age at Birth</a> <a href="#">Last Menstrual Period (LMP)</a> <a href="#">M3 Results</a> - evidence-based, 27 question, patient rated cross cutting mental	Quality reporting relies heavily on many of these "Comment" level elements and HL7 recommends this should be added to USCDI v3.  <a href="#">Estimated Date of Delivery</a> <a href="#">Gestational Age</a> <a href="#">Gestational Age at Birth</a> <a href="#">Last Menstrual Period (LMP)</a>

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<p>health assessment</p> <p><a href="#">Medication Administrations Report (Flowsheet)</a></p> <p><a href="#">Number Fetal Deaths This Delivery</a></p> <p><a href="#">Pregnancy Status</a></p> <p><a href="#">Questionnaire</a></p> <p><a href="#">Tumor Behavior</a></p> <p><a href="#">Tumor Clinical Grade</a></p> <p><a href="#">Tumor Histologic Type</a></p> <p><a href="#">Tumor Laterality</a></p> <p><a href="#">Tumor Primary Site</a></p>	
Patient Demographics	<p><a href="#">Current Address</a></p> <p><a href="#">Date of Birth</a></p> <p><a href="#">Email Address</a></p> <p><a href="#">Ethnicity</a> Both standards are required</p> <ul style="list-style-type: none"> <li>The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997</li> </ul>	<p>HL7 recommends that Ethnicity codes include (from null flavor) "Unknown" and "asked but not answered" from <a href="http://build.fhir.org/ig/HL7/US-Core/ValueSet-omb-race-category.html">http://build.fhir.org/ig/HL7/US-Core/ValueSet-omb-race-category.html</a></p> <p>HL7 recommends alignment with the US Core Patient profile.</p>

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<ul style="list-style-type: none"> <li>• CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</li> <li>• Adopted at 45 CFR 170.207(f)</li> </ul> <p><a href="#">First Name</a></p> <p><a href="#">Gender Identity</a> Gender Identify must be coded in accordance with SNOMED CT® and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor, attributed as follows:</p> <ul style="list-style-type: none"> <li>• Male. 446151000124109</li> <li>• Female. 446141000124107</li> <li>• Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005</li> <li>• Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001</li> <li>• Genderqueer, neither exclusively male nor female. 446131000124102</li> <li>• Additional gender category or other, please specify. nullFlavor OTH</li> </ul>	



Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<ul style="list-style-type: none"> <li>Choose not to disclose. nullFlavor ASKU</li> <li>Adopted at 45 CFR 170.207(o)(2)</li> </ul> <p><a href="#">Last Name</a></p> <p><a href="#">Middle Name (including middle initial)</a></p> <p><a href="#">Phone Number</a></p> <ul style="list-style-type: none"> <li>ITU-T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation - General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses, February 2001, <b>and</b></li> <li>ITU-T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human</li> </ul>	

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<p>Factors, International operation - Numbering plan of the international telephone service, The international public telecommunicatio n numbering plan, November 2010</p> <ul style="list-style-type: none"> <li>Adopted at 45 CFR 170.207(q)(1)</li> </ul> <p><a href="#">Phone Number Type</a></p> <p><a href="#">Preferred Language</a></p> <p>Request for Comment (RFC) 5646, “Tags for Identifying Languages”, September 2009</p> <p>Adopted at 45 CFR 170.207(g)</p> <p><a href="#">Previous Address</a></p> <p><a href="#">Previous Name</a></p> <p><a href="#">Race</a> Both standards are required</p> <ul style="list-style-type: none"> <li>The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity,</li> </ul>	

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<p>Statistical Policy Directive No. 15, as revised, October 30, 1997</p> <ul style="list-style-type: none"> <li>• CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</li> <li>• Adopted at 45 CFR 170.207(f)</li> </ul> <p><a href="#">Sex (Assigned at Birth)</a></p> <p>Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows:</p> <ul style="list-style-type: none"> <li>• Female. F</li> <li>• Male. M</li> <li>• Unknown. nullFlavor UNK</li> </ul> <p>Adopted at 45 CFR 170.207(n)</p> <p><a href="#">Sexual Orientation</a> Sexual orientation must be coded in accordance with SNOMED CT® and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor, attributed as follows:</p> <ul style="list-style-type: none"> <li>• Lesbian, gay or</li> </ul>	

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<p>homosexual. 38628009</p> <ul style="list-style-type: none"> <li>• Straight or heterosexual. 20430005</li> <li>• Bisexual. 42035005</li> <li>• Something else, please describe. nullFlavor OTH</li> <li>• Don't know. nullFlavor UNK</li> <li>• Choose not to disclose. nullFlavor ASKU</li> <li>• Adopted at 45 CFR 170.207(o)(1)</li> </ul> <p><a href="#">Suffix</a></p>	
	<p><b>Level 2:</b></p> <p><a href="#">Birth time</a></p> <p><a href="#">Deceased date</a></p> <p><a href="#">Identifier</a></p> <p><a href="#">Medicare Patient Identifier</a></p> <p><a href="#">Mother's Maiden Name</a></p> <p><a href="#">Multiple Birth Order</a></p> <p><b>Level 1:</b></p> <p><a href="#">Medical Record Number</a></p> <p><a href="#">Next of Kin Name</a></p> <p><a href="#">Next of Kin Relationship</a></p>	HL7 notes birthtime is important for neonatal and newborns.

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
	<a href="#">Patient Address Use Period</a> <a href="#">Patient Marital Status</a> <a href="#">Patient Social Security Number</a> <a href="#">Patient's Primary Care Provider</a> <b>Comment:</b> <a href="#">Current and Previous Address</a> <a href="#">Income</a> <a href="#">Insurance Status</a> <a href="#">Patient Vital Status</a>	
Problems	<a href="#">Date of Diagnosis</a> <a href="#">Date of Resolution</a> <a href="#">Problems</a> <a href="#">SDOH Problems/Health Concerns</a>	
	<b>Level 2:</b> <a href="#">Date of Onset</a> <a href="#">SNODENT</a> <b>Comment:</b> <a href="#">Disease Trend</a>	<p>HL7 notes Date of Onset (when the Physician determines it) can be useful for quality measure logic.</p> <p>HL7 recommends adding a Dental Findings data class to reflect the discrete dental condition/problem findings and dental observations using SNODENT as an optional terminology for dental. Examples are conditions such as dental caries lesions and measurements such as periodontal probing depths, etc. that would be</p>

Data Class	USCDI v2 (Published)	HL7 Recommendations with Rationale, Use Case and Other Information
		conveyed using SNODENT <sup>1</sup> as approved by the HL7 Terminology Authority (HTA) and included in the HL7 Dental Data Exchange IGs (CDA and FHIR), where SNODENT is specified as an optional terminology.